Site visit inspection report on performance against HTA quality standards
University Hospital of North Tees
HTA licensing number 12446

Licensed under the Human Tissue Act 2004 for the

- **making of a post mortem examination;**
- **removal from the body of a deceased person (otherwise than in the course of an anatomical examination or post mortem examination) of relevant material of which the body consists or which it contains, for use for a scheduled purpose other than transplantation; and**
- **storage of the body of a deceased person or relevant material which has come from a human body for use for a scheduled purpose**

16 and 17 August 2011

Executive Summary

A routine site visit inspection of University Hospital of North Tees and its associated satellite, University Hospital of Hartlepool, (together: 'the establishment'), was carried out by the HTA on 16 and 17 August 2011.

The establishment was found to meet most of the HTA standards across the four areas of: consent; governance and quality; premises, facilities and equipment; and disposal. Two minor shortfalls were found in relation to consent.

Examples of strengths and good practice are included in the concluding comments section of the report.

The HTA found the Designated Individual, the Licence Holder, the premises and the practices to be suitable in accordance with the requirements of the legislation.

All reports of HTA inspections carried out from 1 November 2010 are published on the HTA's website.

Background to the establishment and description of inspection activities undertaken

This inspection covered the licensable activities, under HTA licence number 12446, at the University Hospital of North Tees (UHNT; the 'hub') and the University Hospital of Hartlepool (UHH; the 'satellite'). Both hospitals are part of North Tees and Hartlepool NHS Foundation Trust. In total, approximately 550 post mortem (PM) examinations are undertaken at the establishment each year. The vast majority of these are conducted under the authority of HM Coroners for Teesside and Hartlepool. UHNT conducts approximately three hospital, consented, PM examinations each year. Although UHH maintains provision for conducting hospital, consented, PM examinations, there has been no such activity since 2006. The establishment is equipped to conduct high risk PM examinations, and hosts visiting pathologists including Home Office pathologists. Paediatric PM examinations are referred to other HTA-licensed establishments. Consent for paediatric PM examinations is taken by trained staff at UHNT using consent documentation provided by the establishment that conducts the PM examination. Two minor shortfalls relating to this consent documentation are detailed below (refer to: 'HTA standards not met').

The premises covered by the licence were extended in July 2008 to include the Accident and Emergency Department of UHNT with respect to the removal of relevant material from deceased children.

Relevant material removed during PM examination is processed within the clinical pathology laboratory at UHNT. There is provision for relevant material to be transferred to specialist external pathologists if necessary. The clinical pathology laboratory is subject to Clinical Pathology Accreditation (CPA). The last full inspection was conducted in 2009. A recent monitoring visit was conducted in July 2011 and resulted in 2 non critical non conformities and advisory comments.

This was the second, routine, HTA site visit inspection. The timetable for inspection was developed with due consideration of the establishment's licensing history and pre inspection discussion with the Designated Individual (DI). The scope of the inspection included a visual inspection of the licensed premises comprising the mortuary at UHNT and at UHH, the clinical pathology laboratory at UHNT and the paediatric resuscitation room within the Accident and Emergency Department at UHNT. Relevant policies, standard operating procedures and records were reviewed and interviews were conducted with a Senior Coroner's Officer and members of staff working under the licence.

A traceability audit was carried out as follows:

At UHNT the details of a body in storage was compared against entries in relevant documents and on the mortuary computerised database.

Also at UHNT, three cases where tissue had been taken at PM examination were traced into the clinical pathology laboratory. These cases included a hospital, consented, PM examination and 2 coronial PM examinations. During this traceability audit a minor discrepancy was noted in that, for one case, not all the slides could be accounted for. To check whether this was a systemic issue, the traceability audit was extended to review a further three cases. All blocks and slides associated with this extended audit were traceable. Nevertheless the establishment has introduced enhanced procedures for tracking slides within the clinical pathology laboratory.

At UHH the details of a body in storage were compared against relevant entries. In addition, records and material relating to one coronial PM examination, where tissue had been taken for examination, were traced back to the clinical pathology laboratory at UHNT. All tissue was traceable with no anomalies or discrepancies.

Meeting the HTA's licensing standards

The HTA developed its licensing standards with input from its stakeholders, in order to ensure the safe and ethical use of human tissue and the dignified and respectful treatment of the deceased. The HTA expects licensed establishments to meet these standards.

This is an exception-based report: only those standards that have been assessed as not met are included. Where the HTA determines that a licensing standard is not met, the level of the shortfall will be classified as 'Critical', 'Major' or 'Minor' (see Appendix 3: Classification of the level of shortfall).

Unless otherwise advised, the establishment is required to inform the HTA within 14 days of the receipt of the final report of the corrective and preventative actions that will be taken to ensure that the improvements are addressed. A template for this purpose is provided as a separate Word document.

HTA standards not met

Consent

Standard	Inspection findings	Level of shortfall
C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the Code of Practice.	The paediatric PM examination consent form does not reflect HTA requirements regarding retention of tissue in the form of wax-embedded blocks and slides. The consent form, provided to UHNT by the HTA-licensed establishment where the PM examination takes place, is out of date and refers to storage of blocks and slides 'indefinitely as part of the medical record'. Notes within the consent form refer to use of retained blocks and slides for further tests relating to cause of death or illness. However, the notes do not make clear that consent is required for tissue samples to be retained and used for a 'scheduled purpose' under the HT Act. As such, the consent form does not give the parents the option to choose, or refuse, to allow the hospital to retain blocks and slides for a scheduled purpose following completion of the PM examination. The HTA considers there to be a low risk of invalid consent being taken as, although the forms provided to the parents of the deceased are out of date, the training of those who are responsible for taking consent includes current legislative requirements. Furthermore, the relevant Trust policies and procedures have been updated to reflect HTA requirements.	**Minor**
C2 Information about the consent process is provided and in a variety of formats.	In addition to the consent form referred to above, the establishment responsible for conducting paediatric PM examinations has provided a guidance leaflet for parents, which is used by staff at UHNT when taking consent. This guide is out of date in that it does not reference the HT Act 2004, the HTA or HTA Codes of Practice and contains reference to retention of blocks and slides without specifying the need for consent and without reference to retention for 'scheduled purpose(s)' under the HT Act.	**Minor**

Advice

Below are matters which the HTA advises the DI to consider.

No.	Standard	Advice
1.	C2 & C3	The DI is advised to conduct a review of current training material for those taking consent, together with the patient information literature given to families of the deceased, to ensure that the information is consistent with the requirements of the HTA's Code of Practice on Consent (September 2009). This should include liaison with the DI at the HTA licensed establishment where paediatric PM examinations take place in connection with literature provided by that establishment.
2.	GQ1	The DI is advised to conduct a review of the controlled documents held in the paediatric resuscitation room within the Accident and Emergency Department to ensure that only the current standard operating procedures (SOPs) are available to those carrying out licensable activities. During inspection it was noted that a superseded version of one SOP was still available in the area.
3.	GQ1	The DI is advised to update the SOP relating to the removal of tissue samples from children in cases of sudden, unexpected, death to include reference to: • The Designated Individual(DI) and responsibilities of the DI • The location of licensed premises where tissue can be removed • The procedure for reporting serious untoward incidents to the HTA
4.	GQ2 & GQ7	The DI is advised to extend the formal schedules of audit and risk assessment to, routinely, include the licensable activities within the paediatric resuscitation room of the Accident and Emergency Department.
5.	GQ4 & GQ2	The DI is advised to maintain diligence with respect to routine use of forms and the recording of information within the mortuary. In particular: • The occasional use of correction fluid on paper records may compromise the integrity of recorded information. When a correction is required, a single line can be drawn through the text and the correct entry made without obliterating the corrected record. It is good practice for corrected entries to be initialled by the individual making the change. • The occasional practice of photocopying photocopies of standard forms used in the mortuary results in poor legibility and the potential for incomplete and/or incorrect data entry. It is noted that the establishment has recently implemented a procedure to only photocopy additional forms from an original master. • The occasional omission of information that is routinely required on forms or in registers. Missing information, signified by occasional blank boxes on standard forms, should be addressed on a daily basis during routine checks. Missing entries should also be addressed during horizontal audits of records. Review of records dating back to 2009 and 2010 identified occasional examples of all of the above practices. It is noted that the trend of occurrence indicates an improved level of compliance over time. However, the DI is advised to continue to review standards of record keeping as part of the ongoing audit schedule.
6.	D1	The DI is advised to review SOPs on disposal of tissue from the deceased to ensure that the procedures reflect the requirement to record time, place, method and reason for disposal in line with paragraph 31 of the HTA code of practice 5 on disposal.

7.		The DI is advised to liaise with the Coroners in each of the coronial districts with a view to revising the form that provides relatives of the deceased with options for retention, return, repatriation or disposal of tissue, taken during PM examination, once the Coroner's jurisdiction has ended. Reference to retention of blocks and slides by the hospital "as part of the medical record" should be replaced by reference to retention for a scheduled purpose such as "obtaining further scientific or medical information".

Concluding comments

The HTA found the Designated Individual, the Licence Holder, the premises and the practices to be suitable in accordance with the requirements of the legislation.

The establishment demonstrates a strong commitment to maintaining the dignity of the deceased and the security and care of the deceased whilst in its care. There is also evidence of sensitivity to the needs of the families of the deceased and good interaction with the bereavement support team.

The DI has a sound understanding of the HTA standards and has established a robust governance and quality structure to maintain oversight of operations. This includes good use of the role of HTA Person Designated across the areas of clinical pathology, mortuary and quality management and within the paediatric resuscitation room of the Accident and Emergency Department. The DI keeps up to date with HTA communications and requirements and communicates well with colleagues. There are demonstrably good links with the Coroners and the Coroners' Officers.

The establishment benefits from the role and activities of a Quality Manager. There is evidence of effective audit and risk assessment processes. There is good communication across the teams working under the licence and with those whose jobs impact on licensable activities. This is demonstrated by the effective use of 'mortuary awareness sessions'. There is evidence of a culture of continuous improvement with the existence of regular user group meetings with funeral directors and the request for feedback, for example, through a user group survey exercise conducted towards the end of 2010. Staff working under the licence look to keep in touch with current trends and share experience with other licensed establishments through participation in regional meetings.

The HTA support formal implementation of additional procedural steps to file slides on a specific tray with an associated form to record details of slides that have been returned following examination by the Consultant Pathologist. This new procedure for filing slides was introduced during the course of the inspection. Its introduction will enhance the existing process for ensuring traceability of slides taken during PM examination

The premises are well maintained and have benefitted from improvements made since the previous HTA inspection.

Report sent to DI for factual accuracy: 7 September 2011

Report returned from DI: 21 September 2011

Final report issued: 31 October 2011

Once the establishment has been able to comment on the factual accuracy of the report, it will be published on the HTA website.

Appendix 1: HTA inspection process

The Human Tissue Authority regulates the removal, storage, and use of human bodies, body parts, organs and tissue for activities such as research, transplantation, and education and training. The legal requirements for establishments which carry out such activities are set out in the Human Tissue Act 2004 and The Human Tissue Act 2004 (Ethical Approval, Exceptions from Licensing and Supply of Information about Transplants) Regulations 2006.

We license establishments in England, Wales and Northern Ireland that carry out these activities, and inspect them to make sure legal requirements are met.

Inspections

We use the term 'inspection' to describe when we:

- visit an establishment to meet with staff, view premises and facilities, and review policies and procedures (a site-visit inspection); or
- assess written information we have requested from an establishment (a desk-based assessment / inspection).

We carry out inspections to assess if the Designated Individual (DI) is suitable to supervise the activity covered by the licence, as it is their responsibility to ensure that:

- other staff working under the licence are suitable;
- suitable practices are used when carrying out the activity; and
- the conditions of the licence are met.

We also need to be satisfied that the licence applicant or holder, the establishment's premises, and the practices relating to licensed activities, are suitable.

To help us reach our decisions, we have developed standards under four headings: Consent; Governance and Quality; Premises, Facilities and Equipment; and Disposal.

After every site visit inspection, we write a report documenting our findings. Where we find a particular standard is not fully met, we will describe the level of the shortfall as 'Critical', 'Major' or 'Minor'. In most cases, it will be the responsibility of the DI to seek the HTA's agreement on how they will address the identified shortfalls. More information about the classification of shortfalls can be found in Appendix 3.

The majority of our site-visit inspections are announced. If we have concerns about an establishment, we can also undertake an unannounced site visit inspection.

You can find reports for site visit inspections which took place after 1 November 2010 on our website.

Appendix 2: HTA standards

Standards which are not applicable to this establishment have been highlighted.

Consent standards
C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the code of practice
• There is a documented policy which governs consent for post-mortem examination and the retention of tissue and reflects the requirements of the HT Act and the latest version of the HTA Code of Practice on consent. • There is a documented SOP detailing the consent process (including who is able to take consent, what training they must receive, and what information must be provided to those giving consent for post-mortem examination). • There is written information about the consent process (provided to those giving consent), which reflects the requirements of the HT Act and the latest version of the HTA Code of Practice on consent.
C2 Information about the consent process is provided and in a variety of formats
• Relatives are given an opportunity to ask questions. • Relatives are given an opportunity to change their minds and is it made clear who should be contacted in this event. • Information contains clear guidance on options for how tissue may be handled after the post-mortem examination (repatriated with the body, returned to the family for burial/cremation, disposed of or stored for future use). • Where consent is sought for tissue to be retained for future use, information is provided about the potential uses in order to ensure that informed consent is obtained. • Information on the consent process is available in different languages and formats, or there is access to interpreters/translators.
C3 Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent
• There is a training programme for taking consent for post-mortem examination and tissue retention which addresses the requirements of the HT Act and HTA code of practice on consent. • Refresher training is available (e.g. annually). • Attendance at consent training is documented. • If untrained staff are involved in consent taking, they are always accompanied by a trained individual.

Governance and quality system standards

GQ1 All aspects of the establishments work are supported by ratified documented policies and procedures as part of the overall governance process

- Documented policies and SOPs cover all mortuary/laboratory procedures relevant to the licensed activity. These may include:
    - post-mortem examination, including the responsibilities of the APTs and Pathologists (e.g. evisceration) and management of high risk cases
    - record keeping
    - receipt and release of bodies, which reflect out of hours arrangements
    - lone working in the mortuary
    - transfer of bodies and tissue (including blocks and slides) to other establishments or off site
    - ensuring that tissue is handled in line with documented wishes of the relatives
    - disposal of tissue (including blocks and slides)

  (Note that individual SOPs for each activity are not required. Some SOPs will cover more than one activity.)
- Policies and procedures are regularly reviewed (for example, every 1-3 years).
- There is a system for recording that staff have read and understood the latest versions of these documents.
- Deviations from documented SOPs are recorded and monitored.

GQ2 There is a documented system of quality management and audit

- There is a quality manual which includes mortuary activities.
- Policies and SOPs are version controlled (and only the latest versions available for use).
- There is a schedule for audits to be carried out (which may include vertical and/or horizontal audits).
- Audits include compliance with documented procedures, records (for completeness) and traceability.
- Audit findings document who is responsible for follow up actions and the timeframe for completing those actions.
- Regular audits of tissue being stored at the establishment ensure that staff are fully aware what material is held and why.
- There is a complaints system in place.

GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills

- Staff are appropriately trained/qualified or supervised.
- Staff have annual appraisals.
- Staff are given opportunities to attend training courses, either internally or externally.
- Attendance by staff at training events is recorded.

- There is a documented training programme for new mortuary staff (e.g. competency checklist).

GQ4 There is a systematic and planned approach to the management of records

- There is a system for managing records which includes which records must be maintained, how they are backed up, where records are kept, how long each type of record is retained and who has access to each type of record.
- There are documented SOPs for record management.

GQ5 There are documented procedures for donor selection and exclusion, including donor criteria.

GQ6 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail

- Bodies are tagged/labelled upon arrival at the mortuary.
- There is a system to track each body from admission to the mortuary to release for burial or cremation (e.g. mortuary register, patient file, transport records).
- Organs or tissue taken during post mortem examination are fully traceable, including blocks and slides. The traceability system ensures that the following details are recorded:
    - material sent for analysis on or off-site, including confirmation of arrival
    - receipt upon return to the laboratory or mortuary
    - number of blocks and slides made
    - repatriation with a body
    - return for burial or cremation
    - disposal or retention for future use.
- Multiple identifiers used, including at least one unique identifier (e.g. post mortem number, name, dates of birth/death, etc) to identify bodies and tissue.

GQ7 There are systems to ensure that all adverse events, reactions and / or incidents are investigated promptly

- Staff are trained in how to use the incident reporting system.
- Staff know how to identify incidents and near-misses which must be reported, including those that must be reported to the HTA
- The incident reporting system clearly outline responsibilities for reporting, investigating and follow up for incidents.
- The incident reporting system ensures that follow up actions are identified (i.e. corrective and preventative actions) and completed.
- Information about incidents is shared with all staff (including the reporter) to avoid repeat errors.

GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately

- All procedures related to the licensed activities (as outlined in standard GQ1) are risk assessed.
- Risk assessments include risks associated with non-compliance with HTA standards as well as health and safety risks.
- Risk assessments are reviewed regularly (along with SOPs), for example every 1-3 years.
- Risk assessments include how to mitigate the identified risks; this includes actions that need to be taken, who is responsible for each action, deadlines for completing actions and confirmation that actions have been completed.

Premises, facilities and equipment standards

PFE1 The premises are fit for purpose

- There is sufficient space for the activities to be carried out.
- Refrigerated storage units are in good working condition and well maintained.
- Surfaces are made of non-porous materials.
- The premises are in reasonable condition (structure and cleanliness of floors, walls, entranceways).
- The premises are secure (e.g. there is controlled access to bodies, tissue, equipment and records).

PFE 2 Environmental controls are in place to avoid potential contamination

- There is clear separation of clean, transitional and dirty zones (e.g. doors, floor markings, signs).
- There is appropriate PPE available and routinely worn by staff.
- There is adequate critical equipment and/or PPE available for high risk post mortems.
- There are documented cleaning and decontamination procedures.
- There are documented cleaning schedule and records of cleaning and decontamination.

PFE3 There are appropriate facilities for the storage of bodies, body parts, tissues and cells, consumables and records.

- There is sufficient capacity for storage of bodies, organs and tissues.
- Temperatures of fridges and freezers are monitored on a regular basis.
- There are documented contingency plans in place should there be a power failure, or overflow.
- Bodies are shrouded whilst in storage.
- There is separate storage for infants and babies. If not, special measures are taken for the bodies of infants and babies.

PFE 4 Systems are in place to protect the quality and integrity of bodies, body parts, tissues and cells during transport and delivery to a destination

- There are documented procedures for transportation of bodies and tissue anywhere outside the mortuary (e.g. lab, other establishment), including record-keeping requirements.
- There are written agreements in place with any external parties (e.g. undertaker, or courier) who transport bodies and/or tissue behalf of the establishment (laboratory or mortuary).

  (Note that coroners usually have their own agreements with external parties for transportation bodies and tissue; however, documentation for traceability purposes must still be maintained by the establishment for these cases.)

PFE5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored

- Items of equipment in the mortuary are in a good condition and appropriate for use:
  - fridges / Freezers
  - hydraulic trolleys
  - post mortem tables
  - hoists
  - saws (manual and/or oscillating)
  - PPE for high risk cases (e.g. respirators)
- The use of porous materials is kept to a minimum and has been risk assessed
- Maintenance/service records are kept for equipment, including fridges/freezers, trolleys, post mortem tables (if downdraught) and post mortem suite ventilation.

(Note: These records may be held by the mortuary or centrally by the Trust, e.g. Estates Department.)

Disposal Standards

D1 There is a clear and sensitive policy for disposing of human organs and tissue

- There is a documented Trust or mortuary/laboratory policy for the disposal of human tissue, which reflects the requirements of the HTA code of practice on disposal.
- There are documented procedures for disposal of human tissue, including blocks and slides.

D2 The reason for disposal and the methods used are carefully documented

- There are systems in place that ensure tissue is disposed of in accordance with the documented wishes of the deceased person's family.
- Disposal records include the date, method and reason for disposal.
- Tissue is disposed of in a timely fashion.

  (Note: this means that tissue is disposed of as soon as reasonably possible once it is no longer needed, e.g. when the coroner's or police authority ends or consented post-mortem examination is complete.)

Appendix 3: Classification of the level of shortfall

Where the HTA determines that a licensing standard is not met, the improvements required will be stated and the level of the shortfall will be classified as 'Critical', 'Major' or 'Minor'. Where the HTA is not presented with evidence that an establishment meets the requirements of an expected standard, it works on the premise that a lack of evidence indicates a shortfall.

The action an establishment will be required to make following the identification of a shortfall is based on the HTA's assessment of risk of harm and/or a breach of the HT Act or associated Directions.

1. **Critical shortfall:**

   A shortfall which poses a significant risk to human safety and/or dignity or is a breach of the Human Tissue Act 2004 (HT Act) or associated Directions

   or

   A combination of several major shortfalls, none of which is critical on its own, but which together could constitute a critical shortfall and should be explained and reported as such.

   A critical shortfall may result in one or more of the following:

   (1) A notice of proposal being issued to revoke the licence

   (2) Some or all of the licensable activity at the establishment ceasing with immediate effect until a corrective action plan is developed, agreed by the HTA and implemented.

   (3) A notice of suspension of licensable activities

   (4) Additional conditions being proposed

   (5) Directions being issued requiring specific action to be taken straightaway

2. **Major shortfall:**

   A non-critical shortfall that:

   - poses a risk to human safety and/or dignity, or
   - indicates a failure to carry out satisfactory procedures, or
   - indicates a breach of the relevant CoPs, the HT Act and other relevant professional and statutory guidelines, or
   - has the potential to become a critical shortfall unless addressed

   or

   A combination of several minor shortfalls, none of which is major on its own, but which, together, could constitute a major shortfall and should be explained and reported as such.

3. **Minor shortfall:**

   A shortfall which cannot be classified as either critical or major, but which indicates a departure from expected standards.

   This category of shortfall requires the development of a corrective action plan, the results of which will usually be assessed by the HTA either by desk based or site visit.

Follow up actions

A template corrective and preventative action plan is available as a separate Word document. You must complete this template and return it to the HTA within 14 days of the issue of the final report.

Based on the level of the shortfall, the HTA will consider the most suitable type of follow-up of the completion of the corrective and preventative action plan. This may include a combination of

- a follow-up site-visit inspection
- a request for information that shows completion of actions
- monitoring of the action plan completion
- follow up at next desk-based or site-visit inspection.

After an assessment of your proposed action plan you will be notified of the follow-up approach the HTA will take.